REMARKS

Claims 1, 3-8, 10-17 and 19-24 are pending in the application. Claims 7, 10, 11, 16, 19 and 22 have been amended. The Examiner has indicated that claims 1 and 3-6 are allowable.

Claims 10 and 11 have been objected to. Appropriate correction has been made.

Claims 7, 8, 10-17 and 19-24 have been provisionally rejected under the judicially created doctrine of obviousness type double patenting. Applicants filed a Terminal Disclaimer on July 31, 2002. This amendment is now believed overcome.

Claims 7, 8, 12-14, 16, 17 and 21 have been rejected under 35 USC.§102(b) or in the alternative under 35 USC§103(a) over Huang et al. Applicants respectfully traverse this rejection.

The present invention as claimed in claims 7, 8, 12-14, 16, 17 and 21 is directed to a composition comprising a pharmaceutical dosage unit of a pharmaceutically acceptable carrier containing an immune system-potentiating amount of at least one member selected from the group consisting of thymosin and immune system-potentiating fragments of thymosin in combination with an anti-hepatitis C viral effective amount of at least one α-interferon, said pharmaceutical dosage unit being capable of promoting *in vivo* inactivation of hepatitis C virus when administered to mammals infected with said virus (as amended).

The present invention is improved over previous compositions because it combines (1) an anti hepatitis C viral amount α-interferon with (2) thymosin in a pharmaceutical dosage unit that promotes *in vivo* inactivation of hepatitis C.

Huang et al. discloses a pharmaceutical composition of interferon and thymosin. There is no disclosure of a combination of "α-interferon" and thymosin. Huang et al. also does not disclose in its composition an "anti-hepatitis C viral effective amount of at least one α-interferon, said pharmaceutical dosage unit being capable of promoting *in vivo* inactivation of hepatitis C virus when administered to mammals infected with said virus." Hence, Huang et al. does not anticipate claims 7, 8, 12-14, 16, 17 and 21 because it does not disclose these important claimed features.

Claims 10, 11, 15, 19, 20 and 22-24 have been rejected under 35 U.S.C. §103(a) as allegedly obvious over Huang et al, in view of Hoofnagle et al., Goldstein, et al. and Birr et al. Applicant respectfully traverses this rejection.

As stated above, the present invention, as claimed in claims 10, 11, 15, 19, 20 and 22-24 is directed to a composition having in it a combination of (1) α-interferon and (2) thymosin.

Huang et al. is directed to a composition for treating Hepatitis B rather than C. The Examiner makes a very valid point that it does not matter what a composition claim is used for. However, in the case at hand, the rejected claims call for a particular dosage unit of the composition that is not disclosed or suggest by Huang et al. The dosage unit specified in the claims at issue is "an anti-Hepatitis C viral effective amount of at least one α-interferon, said pharmaceutical dosage unit being capable of promoting *in vivo* inactivation of hepatitis C virus." Further, as stated above, Huang et al. also fails to teach the use of α-interferon.

Hoofnagle et al. discloses a composition containing α-interferon. There is no mention of the combination of α-interferon with thymosin. There is also not suggestion of what the proper dosage unit would be or what parameters would be useful to achieve the proper dosage unit for a hepatitis C vaccine containing α-interferon and thymosin.

It would not have been obvious to combine Hoofnagle et al. with Huang et al. because Hoofnagle does not provide the missing disclosure of Huang et al. In order for Hoofnagle to be a proper reference for combination with Huang et al., it would have to suggest the amounts of thymosin and α-interferon used in combination in a single pharmaceutical composition. It does not.

Goldstein et al. discloses that thymosin alpha 1 is immunopotentiating. There is no discussion of using thymosin of any type in combination with α-interferon or what amount constitutes an anti-hepatitis C viral amount or what dosage unit is capable of promoting *in vivo* inactivation of hepatitis C (as set forth in the claims). Hence, Goldstein, et al. also does not make up for the deficiencies of Huang et al. or add anything to Hoofnagle et al. which would have led one of ordinary skill in the art to the claimed invention.

Birr et al. is directed to a method of preparing thymosin α1. Birr et al. suggests using thymosin α1 for treating cancer. There is no discussion combining thymosin with interferon in a single formulation or what amounts to use to inactivate hepatitis C. Thus, Birr et al. does not make up for the deficiencies of Huang et al, Hoofnagle et al or Goldstein et al. and would not have led one of ordinary skill in the art to the present invention.

Further, there is no suggestion in any of the references that a pharmaceutical formulation for hepatitis "B" would work for hepatitis "C." Without this suggestion, there is simply no motivation to combine Hoofnagle et al., Goldstein et al. or Birr et al. with the primary Huang et al. reference cited by the Examiner. Since none of the references, whether taken alone or in combination, indicate how to modify Huang et al. to arrive at a formulation that meets the language in the claims, one of ordinary skill in the art would not have been led to the present invention.

To date, no one has devised a formulation that combines α-interferon and thymosin in a dosage unit that is capable of promoting *in vivo* inactivation of hepatitis C virus or shown that dosage units for hepatitis C are or should be the same as hepatitis B. Hence, this rejection is believed overcome.

The application is now believed to be in condition for allowance. Reconsideration and allowance are respectfully requested.

Respectfully submitted,

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